K012121

OCT 2 4 2001

October 17, 2001

(510k) Summary of Safety and Effectiveness

Pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act, Safety and Effectiveness information is enclosed for the following device:

Device Name: SECUREGARD® Retractable Safety Syringe
Trade Name: SECUREGARD® Syringe
Common Name: Safety Syringe
Classification name: Piston Syringe / Anti-Stick Syringe

Device Class: Class II
Classification Code: MEG

Performance Standard: None established.

Safety and Effectiveness: No new issues safety and effectiveness as relating to hypodermic syringes. The sharps injury prevention feature was demonstrated to be easily and safely activated by the user, and the needle was effectively shielded by the sharps protection feature.

Facility Address: SafeGard Medical Systems (Hungary) KFT
Joszéréncsét tér 15, H-3608
Farkaslyuk, Hungary

Establishment Registration Number: 9616482

Indications for Use: The intended function of the SECUREGARD® Retractable Safety Syringe is to provide a safe and reliable method of intramuscular and subcutaneous injection of medication into a patient. The syringe should not be used for blood collection. The SECUREGARD® Retractable Safety Syringe is also intended to prevent needle stick injuries. In addition, when the syringe user breaks the plunger, reuse of the syringe is prevented.

Substantial Equivalence: The SECUREGARD® Retractable Safety Syringe is substantially equivalent to the SOLOGARD® Locking Plus Syringe. The SECUREGARD is a sterile, single-use, disposable hypodermic syringe with sharps injury and reuse prevention features, It is manufactured in sizes of 0.5, 1, 2, 2.5, 3, 5, 10 and 20 mL volume.

Contact Information:
Pat Grant Jr.
Director Regulatory Affairs
SafeGard Medical Products, Inc
52 Dragon Court
Woburn, MA 01801
Tel. (781) 935 2275
Fax (781) 935 8424

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2001

SafeGard Medical Products, Incorporated
C/O Mr. Mike Dayton
BioMed Research, Incorporated
14802 Hadleigh Way
Tampa, Florida 33624

Re: K012121
Trade/Device Name: SECUREGARD® Retractable Safety Syringes
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: September 21, 2001
Received: October 1, 2001

Dear Mr. Dayton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012121

Indications for Use Statement

510k Number (if known): K012121

Device Name: SECUREGARD® Retractable Safety Syringe

Indications For Use:

The intended function of the SECUREGARD® Retractable Safety Syringe is to provide a safe and reliable method of intramuscular and subcutaneous injection of medication into a patient. The syringe should not be used for blood collection. The SECUREGARD® Retractable Safety Syringe is also intended to prevent needle stick injuries. In addition, when the syringe user breaks the plunger, reuse of the syringe is prevented.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Rebecca Cricenti

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012121